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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,369	03/12/2004	Elena V. Bolchakova	1560.002US1	6361
21186 7590 02/15/2007 SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER HUTSON, RICHARD G	
			ART UNIT 1652	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/15/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/799,369

Applicant(s)

BOLCHAKOVA ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-33, 37-40, 44, 45 and 47-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34, 36, 41-43 and 46 is/are rejected.
- 7) ☒ Claim(s) 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/05/7/06, 8/06
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claims 1-55 are still at issue and are present for examination.

Election/Restrictions

Applicant's election with traverse of Group II, Claims 34-43 and 46, drawn to a nucleic acid polymerase polypeptide, in the paper of 11/16/2006, is acknowledged.

Further restriction is also required under 35 USC 121. Applicants are further required to elect a sequence selected from the group consisting of SEQ ID NOs: 13-28.

The inventions are distinct, each from the other because of the following reasons:

Inventions corresponding to each of the SEQ ID NOs: 13-28 are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the compositions and methods of use of said compositions comprising each of the different SEQ ID NOs: are patentably distinct based on the different structures of each of the different SEQ ID NOs: Each of these different SEQ ID NOs: comprise a chemically unrelated structure capable of separate manufacture, use and effect.

Applicant's additional provisional election to the nucleic acid sequence of SEQ ID NO: 22, in the telephone interview with Scott Bortner, on 1/31/2007, is acknowledged.

Claims 1-33, 37-40, 44, 45 and 47-55 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Applicants filing of the information disclosure statements, filed on 12/27/2005, 7/6/2006 and 8/21/2006, are acknowledged. Those references considered have been initialed.

Specification

The disclosure is objected to because of the following informalities:

Applicants specification states that SEQ ID NO: 22 has Tyr in place of Phe at position 668 and shows the corresponding "Y" underlined on page 57, line 7. This numbering of the amino acid residues of SEQ ID NO: 22 on page 57 does not correspond to applicants disclosure of SEQ ID NO: 22 in the sequence listing. For example the corresponding underlined "Y" residue of page 57, is listed as Tyr residue 665 in the sequence listing, even though the description of SEQ ID NO: 22, in the sequence listing states that "Tyr is used in place of the Phe at position 668".

Appropriate correction or explanation is required.

Claim Objections

Claim 35, 36, 41-43 and 46 are objected to because of the following informalities:

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Claim 35 is objected to because it is drawn to the nucleic acid polymerase of claim 34, when claim 34 is drawn to a "DNA polymerase polypeptide".

Claim 46 is objected to because it depends from non-elected claim 44.

Claims 36, 41-43 contain non-elected subject matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36, 41-43 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36, 41-43 and 46 are each indefinite in that they each refer to or are dependent from claims that refer to SEQ ID NO: 22. The reference to SEQ ID NO: 22 is indefinite in that as discussed above under the objection to the specification, applicants specification lists two different SEQ ID NO: 22 sequences (the 830 amino acid listed in the sequence listing and the 833 amino acid sequence listed on pages 56 and 57). Thus it is unclear as to which SEQ ID NO: 22 applicants intend to claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 34 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 34 is directed to any possible DNA polymerase polypeptide from *Thermus scotoductus* strain X-1, ATCC Deposit No. 27978. Claim 46 is drawn to any nucleic acid polymerase of made by the method of claim 44. The specification, however, only provides the representative species of that DNA polymerase having the amino acid sequence of SEQ ID NO: 22, encompassed by the claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these polypeptides by any identifying structural characteristics or properties other than that polypeptide having the amino acid sequence of SEQ ID NO:22, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

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Claims 34 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA polymerase having the amino acid sequence of SEQ ID NO: 22 and having DNA polymerase activity, does not reasonably provide enablement for any DNA polymerase polypeptide from *Thermus scotoductus* strain X-1, ATCC Deposit No. 27978. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 34 and 46 are so broad as to encompass any DNA polymerase polypeptide from *Thermus scotoductus* strain X-1, ATCC Deposit No. 27978 or any polymerase made by the method of claim 44. While it acknowledged that the *Thermus scotoductus* strain X-1, ATCC Deposit No. 27978 is public ally available, the scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims, including any DNA polymerase polypeptide from *Thermus scotoductus* strain X-1, ATCC Deposit No. 27978 having an undefined activity. The claims rejected under

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this section of U.S.C. 112, first paragraph, do not place any functional limits on the claimed polypeptides. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to that DNA polymerase polypeptide from *Thermus scotoductus* strain X-1, ATCC Deposit No. 27978 having the amino acid sequence of SEQ ID NO: 22 and having DNA polymerase activity.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any polymerase polypeptide from *Thermus scotoductus* strain X-1, ATCC Deposit No. 27978, because the specification

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does not establish: (A) regions of the polypeptide structure which may be modified without effecting polymerase or desired activity; (B) the general tolerance of polymerase polypeptide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a polymerase polypeptide with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the desired or required activity and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to arrive at the majority of those polypeptides of the claimed genus having an undefined activity.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of any polymerase polypeptide. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in

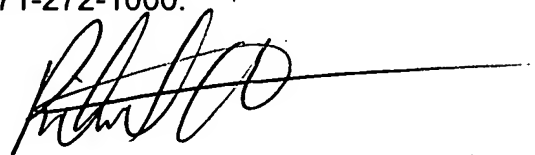
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the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', followed by a long horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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2/1/2007